The development and implementation of an outcomes database for imaging-guided therapeutic musculoskeletal injections

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Abstract: OBJECTIVES: To present the process of creating an imaging-guided injections outcomes database and to reflect on how this database has affected the scientific activities of the radiology department. MATERIALS AND METHODS: The literature was searched to identify studies on the effectiveness of musculoskeletal therapeutic injections, areas where research is lacking, and relevant outcome measures. Validated outcome measures were chosen and tested in a pilot study. Data collection time points of 1 day, 1 week and 1 month post-injection were determined and the post-pilot study postal questionnaires were created. The data collection process began and has been ongoing for over 4 years. Critical reflection on the process and outcomes from the database occurred. RESULTS: The 9 steps to creating this outcomes database are presented. The numerical rating scale for pain (NRS) and the Patient's Global Impression of Change (PGIC) were identified as the most valid, reliable, and time-effective outcome measures. At most, 50% of patients return their postal questionnaire. The database has facilitated the publication of numerous research projects. CONCLUSIONS: Setting up an outcomes database is straightforward and productive. The NRS and PGIC were considered the most useful outcome measures. This database facilitated critical reflection on current practice and provides the foundation for several research studies.

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TECHNICAL REPORT

The development and implementation of an outcomes database for imaging-guided therapeutic musculoskeletal injections

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Introduction

Medicine is currently being pressed to contain soaring health-care costs without compromising the quality of health care delivered [1–3]. Increasing pressure will be placed on clinicians to monitor their performance and provide evidence to governments, insurers, and patients with regard to the outcomes and costs related to their various treatments [1, 2]. Some countries have already started this process with the goals to improve quality of care and encourage practice according to national standards and guidelines [2, 4, 5]. In the future, physicians will likely see at least some of their pay based on the quality and efficiency of their services.

Measuring patient outcomes from medical interventions could and perhaps should become a routine part of daily clinical practice. This would provide a quality assurance program to help clinicians, departments or practices monitor, analyze, and improve patient outcomes on a continuous basis [6]. Many validated outcome measures (questionnaires) are available in a variety of languages, specific to the condition or anatomical region treated [1, 2, 7]. Some of these questionnaires are quite long, however, and clinicians, their office staff, and patients are often reluctant to use them in daily clinical practice because of the time required for completion. Still, these longer outcome measures are used routinely in research studies to evaluate the effectiveness of medical treatments, with the results often having profound positive consequences for patients and physicians. Finding the right balance of appropriate, responsive, yet short outcome measures for daily clinical

practice is critical if the implementation of such a quality assurance program is to be successful.

Recognizing the likely eventuality that providing outcome data for the treatments used would become mandatory, the radiology department at this specialized orthopedic/rheumatology university hospital was proactive and began the process of implementing a database assessing the outcomes of patients receiving all imaging-guided musculoskeletal (MSK) therapeutic injections in 2009. A review of the relevant literature on databases or quality assurance assessment measures for interventional pain management found only two recent papers addressing this issue [4, 6] with pain levels only measured immediately after the procedures. No longer term outcomes were measured.

The original purposes for creating a database for outcomes from imaging-guided therapeutic injections were to:

1. Document and assess the outcomes from the various injection sites for quality assurance purposes
2. Reflect on and compare the outcomes from our hospital with those published in available research studies to identify areas needing improvement or areas of good practice
3. Provide a large database for more specific and detailed research projects

Once this database had obtained outcome data for several thousand patients, it was decided to assess its value and critically examine what has been learned. Therefore, the purposes of this paper are to present the process undertaken to create the database for imaging-guided therapeutic musculoskeletal injections at this hospital, and to reflect upon how this database has affected the scientific activities of the radiology department in the hopes that other institutions may decide to implement a similar project.

Materials and methods

In 2008–2009 the radiology department recognized the need to document outcomes of patients undergoing the thousands of imaging-guided musculoskeletal injections being carried out yearly at this university's orthopedic/rheumatology hospital. The first step in the process of creating this outcomes database was to obtain funding. Therefore, a grant proposal was written because the current radiologists, technologists, and other staff did not have the time necessary to devote to this project as well as perform all of their other job requirements. The grant application was successful primarily because of the recognition by the funding agency of the direction that the Swiss government and indeed those of other countries are going in terms of reimbursement for various treatments in healthcare based on outcomes. Once funding had been obtained, the second step in this process involved hiring a radiology research fellow with over 20 years of diagnostic imaging and research experience to take charge of the project (Fig. 1). This position represented only 20 % of a full-time job (i.e., 1 day per week).

Ethics approval was obtained from the hospital and county ethics committees, and all patients signed informed consent.

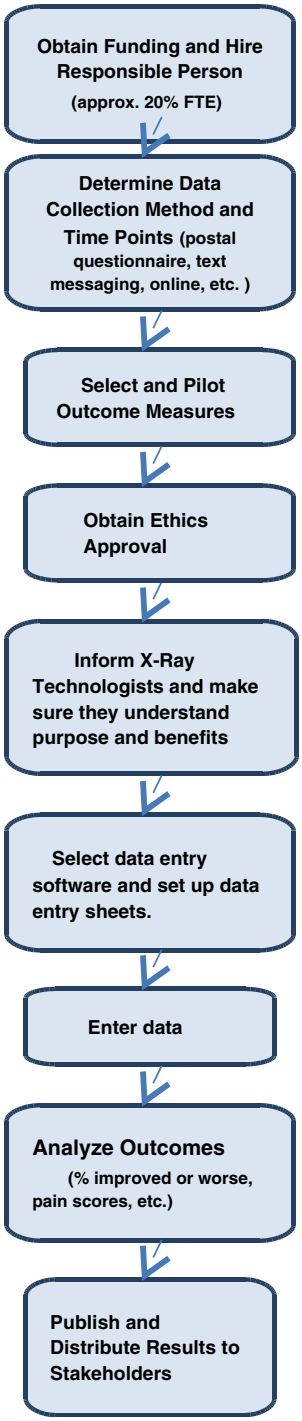

Fig. 1 Flow chart of steps to create the outcomes database for imaging-guided therapeutic musculoskeletal injections

Prior to collecting any data, literature searches were carried out to:

1. Collect and evaluate the research evidence supporting the various musculoskeletal therapeutic injections [8–10]
2. Identify areas in the literature where evidence is lacking [8–14]
3. Collect and evaluate appropriate questionnaire outcome measures (available and validated in German) for the various regions of the body treated

PubMed and the Cochrane databases were used for the literature search with the key words "intra-articular injection," "musculoskeletal injection," "outcomes," "effectiveness," "database," and "quality assurance" inserted alone and in various combinations. The references for the relevant articles obtained were also hand searched. In order to find relevant outcome measures, each anatomical region was inserted separately into these search engines.

Several MSK outcome measures, translated into and validated in German, were identified for each bodily region. The Oswestry questionnaire for low back pain patients receiving lumbar facet injections, lumbar nerve root block injections or epidural injections was selected as most applicable for this bodily region and was piloted in patients receiving these injections. Similarly, the neck disability index was piloted for patients receiving cervical facet joint injections or the new procedure of indirect nerve root blocks [11]. These were the only outcome measures piloted as spinal injections are the most frequent MSK therapeutic injections performed at this hospital. Additionally, all patients in these pilot studies completed the numerical rating scale for pain (NRS), where 0=no pain and 10=unbearable pain, and the 'Patient Global Impression of Change' (PGIC) scale to evaluate over-all "improvement" [15].

After piloting these outcome measures, only the numerical rating scale for pain and the PGIC scale to evaluate over-all "improvement" [15] were used for all MSK injection sites. Patients were requested to use the NRS to rate the severity of their pain relevant to the site to be injected or the site that was injected specifically at the time of questioning. The PGIC scale is a seven-point scale and incorporates factors such as disability and over-all well-being. It has been validated as a "gold standard" for "improvement" [16] and has been used as the primary outcome measure in several recent studies [17–21]. Only patients responding "much better" or "better" (scores of 1 or 2) were categorized as "improved." This was considered the primary outcome for all imaging-guided injection procedures. Patients were instructed to use the PGIC scale specifically for the anatomical site that had received the imaging-guided injection.

Pain levels were measured immediately prior to the injection procedure, and at 20 min after the injection procedure while the patient was in the radiology department. Each patient was then handed an outcomes questionnaire from the radiological technologist to obtain NRS pain levels and PGIC outcome data at 1 day, 1 week, and 1 month after the injection procedure for all musculoskeletal injection sites. These specific time periods were selected as nearly all of the patients were injected with both an anesthetic and a corticosteroid medication. It was desired to assess very short-term outcomes (i.e., 1 day), which may be due to the effect of the anesthetic, as well as medium-term outcomes (i.e., 1 month) that may be the result of the corticosteroid. This questionnaire was in a self-addressed and postage pre-paid envelope and the patients were instructed to return it to the hospital upon completion of the 1-month outcome data. Additionally, it was particularly desired to collect longer term outcome data for two specific injection sites (lumbar inter-laminar epidural injections and cervical indirect nerve root block injections [11]). The research fellow identified these specific patients weekly by accessing the information stored in the hospital computer and their contact information was provided to one of the radiology receptionists. The radiology receptionist was in charge of telephoning these particular patients to collect additional data at 3 months and 1 year after injection. Although desirable, staffing resources did not allow for all patients receiving musculoskeletal injections at other sites to receive follow-up telephone calls 3 months and 1 year after the start of the database.

Data from the returned postal questionnaires and telephone interviews were entered by the research fellow into the Statistical Package for Social Sciences (SPSS) each week according to anatomical injection site. Direct data entry into SPSS provided the opportunity for quick statistical analyses as the data did not have to be copied from another software program and then pasted into SPSS. A weekly calculation of the proportion of patients reporting clinically relevant "improvement" or "worsening" for each injection site was prepared and made available digitally under the name "Pain Database" on the radiology site of the hospital's computer system. No patient identifying features were available on this weekly report. Patients were only identified by number, age, and gender in the SPSS database.

Results

Figure 1 shows the nine steps used to set up this database for therapeutic imaging-guided MSK injections. The Oswestry questionnaire and the Neck Disability Index, although relatively short outcome measures, were found to take up too much time to complete in the pilot studies without disrupting the normal patient flow through the radiology department. Therefore, Fig. 2 shows the two short outcome measures used at all follow-up time points.

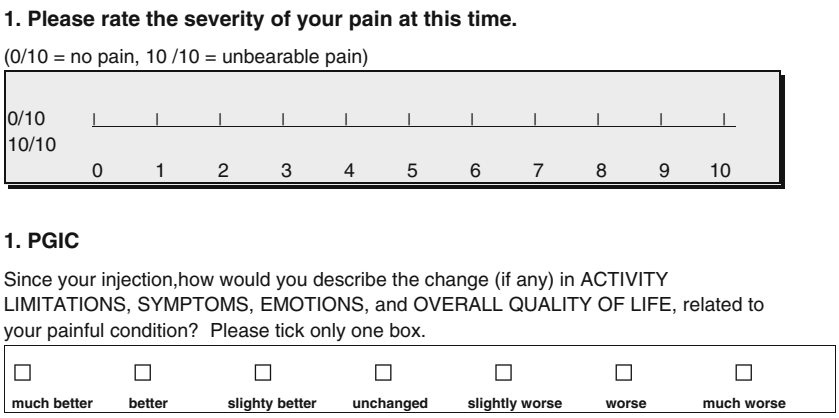

Fig. 2 The two outcome measures consisting of the Numerical Rating Scale (NRS) for pain and the Patient's Global Impression of Change (PGIC) scale used to collect data after imaging-guided therapeutic injections

The database has been growing for the past 4.5 years and continues to grow weekly, with over 5,500 patients included as of November 2013. However, it was found that at the most, 50 % of the patients who are handed these outcome questionnaires actually return them in the post.

Since its inception, 12 scientific papers relating to the database have been published or accepted for publication [8–14, 17, 21–24]. Additionally, 4 medical students have been able to use the database as the foundation for their doctoral research projects and 4 other medical students have used it for their masters' degree research projects. Collaborative research studies with the orthopedic, rheumatological, and chiropractic departments at this hospital have been published using some of the data [17, 22, 23]. One international collaborative research project is nearing completion using data from the lumbar facet injection patients.

Discussion

This paper presents nine steps that can be used to create an outcomes database, not only for imaging-guided MSK injections, but also for other therapeutic interventions. To our knowledge, this is the first paper to present such a process and to routinely collect outcomes for all MSK therapeutic injections beyond the immediate post-injection period [4–6]. Once a substantial number of patients had been included in this database and experience in using it for a few years had been gained, it was desired to share the process of developing this database and to reflect on what worked well and what could work better with this process in the hope that it may stimulate other institutions to create similar databases. A search of the literature found few publications on the routine evaluation of outcomes from these injections, and when available, outcomes were only collected immediately after the procedures [4–6].

The two short outcome measures that were selected for use in developing this database did not disrupt the scheduling and flow of procedures in this busy radiology department and were easy for patients to complete. The NRS for pain is a frequently used outcome measure and the advantages of the PGIC are becoming well recognized. The PGIC has been shown to be a valid and reliable outcome measure in several studies [16–21]. It has also been shown to be a "gold standard" for measuring clinically relevant "improvement" compared with longer outcome measures, including the Oswestry questionnaire [16]. Furthermore, recent studies have shown that other, shorter outcome measures are actually more sensitive to change over time compared with the more traditionally used Oswestry and Neck Disability Index questionnaires [25, 26]. Thus, the department was satisfied with the selection of the outcome measures as the critical information was obtained and it was not taxing for the patient or disruptive to the department.

The radiology department was not satisfied, however, with the fact that half or less than half of the patients returned their 1-month outcomes questionnaires [21, 24]. The research fellow discovered this problem by comparing the number of patients returning their questionnaires with the list of patients having particular injections listed in the computer records. Therefore, it was recognized early on in the development of the database, that the first of any follow-up studies needed to explore whether or not the outcome results obtained from patients who returned these postal questionnaires were an accurate reflection of the outcomes from the various injection procedures. Two of the three studies investigating this have been published [21, 24]. Thus, it was learned that better communication with the patient at the time of giving them the postal questionnaire may have improved the return rate. Alternatively, other data collection methods such as text messaging may be a better way of collecting this type of data [27].

The department also discovered a couple of years into the project that some of the technologists were not routinely handing these questionnaires to all patients as they somehow thought that the project was completed. Better communication between the research fellow and the technologists may have prevented this problem. Certainly, the return rate improved dramatically from a low of only 6 returned questionnaires one

particular week to a consistent 40–50 questionnaires per week immediately after the research fellow made a formal presentation to the technologists covering the results obtained from the database and research studies published relating to it. It is critical to ensure that the technologists fully understand why a database project is started and the potential benefits for the patients in order for them to feel that their contribution to the project is vital. This was an important lesson that was learned.

Since starting this project, 12 research papers using data from this database have been published and several more are currently under review. Eight medical students to date have used the database for their required masters' or doctoral research studies and there has been an increase in collaborative research projects between the various departments in this hospital. The data that are currently available will provide many more opportunities for other research studies in the future in all areas of the musculoskeletal system, with ideas for additional projects continuing to grow.

Because the radiology department has found that the outcomes from these imaging-guided MSK injections vary widely depending upon the injection site, the current focus of the research studies is to compare specific abnormalities found on imaging with patient outcomes. One such study already started is comparing abnormalities found on lumbar spine MRI scans with outcomes from patients who have imaging-guided lumbar nerve root blocks. Another study is looking at specific degenerative changes of the hip on routine radiographs and outcomes from imaging-guided hip injections. The goal is to help referring clinicians and their patients make more informed decisions concerning which patients are more or less likely to have a positive outcome from a particular injection. Other studies are also in process, with the first already published [17]. Future studies plan to investigate whether or not there is a link between specific abnormalities found on the physical examination and outcomes from injections.

Comparison of the outcomes from this hospital with those of other hospitals has not been made at this point, other than looking at studies previously published. Comparing the outcomes from this hospital with those reported in the literature is problematic for two reasons. One is that this hospital, being a specialized orthopedic/rheumatology hospital, attracts more difficult patients who have often been seen by many different physicians and health care professionals before being referred here. The other difficulty in comparing our results with those of other research studies is that many facilities are not routinely administering these injections under imaging guidance, as recommended in the guidelines [8, 9]. Searching for other hospitals with a similarly established database in Europe has just started.

The 1-month and 3-month outcomes obtained from this database have allowed the radiology department to focus on quality assurance issues such as considering why the outcomes for certain anatomical sites are much better than those for other sites, and comparing the outcomes from this hospital with those published from other locations. This has been very advantageous in stimulating ideas for many follow-up research projects, as elaborated upon above, providing data for medical students to complete their research requirements and facilitating collaboration between various medical specialties at this hospital. It is also an advantage that the research fellow is available to supervise the medical students in their various projects using this database, thus removing part of the burden of more senior radiologists. The database will also provide an opportunity for the department in the future to compare outcomes based on the experience of the radiologist, as this is also a teaching hospital.

An obvious disadvantage of starting an outcomes database for any therapeutic intervention is the cost of hiring someone to manage it. At this particular hospital a trained clinician and researcher were chosen rather than a secretary or research assistant. The cost may be somewhat higher for this type of employee, but the advantages lie in the fact that a trained research fellow can write papers, carry out statistical analyses, and supervise post-graduate students. It was found that the job could be done on a 20 % contract. Other associated costs included the printing of the questionnaires and envelopes as well as the postage for the return envelopes. This cost could be avoided if another means of data collection, such as e-mail or text messaging, was used rather than postal questionnaires [27]. As many of the patients in our database are older, it was thought that they may not be as familiar with electronic data collection methods as they would be with traditional paper questionnaires. This will certainly change in the future, however.

Conclusions

The creation and implementation of this outcomes database for imaging-guided musculoskeletal injections has facilitated critical reflection on performance and consideration of ways to improve through additional research studies focusing on specific imaging or clinical findings that may be linked with outcome [28]. It also provides valuable information for referring clinicians and has been a resource for masters and doctoral students to complete their research requirements. The NRS and PGIC were determined to be the most useful outcome measures in terms of time efficiency, validity, and the breadth of information provided, and can even be used in a busy department.

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Conflict of interest The authors declare that they have no conflict of interest.

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